

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	A Protocol for the Development and Acceptability of a Fertility-related Decision Aid for Young Women with Breast Cancer in Portugal.
AUTHORS	Gonçalves, Vânia; Travado, Luzia; Ferreira, PL; Quinn, Gwendolyn

VERSION 1 – REVIEW

REVIEWER	Dr Nancy Baxter and Ms Brittany Speller St Michael's Hospital, University of Toronto Canada
REVIEW RETURNED	17-Apr-2019

GENERAL COMMENTS	<p>Summary</p> <p>Goncalves et al., present a protocol detailing their development and evaluation plan for a Portuguese reproductive health-related decision aid booklet for young breast cancer patients. The team plans to revise a decision aid created by Peate et al. in Australia to the Portuguese context. The development process is multi-phase with the first phase including forward translation of the Australian aid, a literature review and multidisciplinary panel review of the information, a back-translation, and then a qualitative cross-sectional study to assess the adequacy of the content through focus groups with recently diagnosed young breast cancer patients, young breast cancer survivors, and partners of young breast cancer patients.</p> <p>The protocol is generally clear and provides a good overview of the proposed plan for the development and evaluation of the decision aid. Additional detail on the preliminary steps of the development process/ frameworks used to inform their work and a careful review for grammatical errors should be completed prior to publication.</p> <p>Major Comments</p> <ul style="list-style-type: none">• The authors do not provide any information on the literature review process or how expert group consensus during the multidisciplinary panel will occur. This information should be added to Figure 1 to be consistent with the process planned for the focus group analysis (content analysis).o Will the authors adhere to the PRISMA checklist for the literature review? Authors should report on what databases they are searching for the review, year restrictions, inclusion/exclusion details, risk of study bias, data abstraction and synthesis plan.o What consensus strategy will the authors use with the multidisciplinary panel to determine what scientific and cultural aspects of the decision aid should be modified (e.g., Delphi)?
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	<ul style="list-style-type: none"> • The authors should include a reference for content analysis • The authors can cite recent works on oncofertility resources identified in organizations and other decision aids available (examples below) <ul style="list-style-type: none"> o Wang, Y., Anazodo, A., & Logan, S. (2019). Systematic review of fertility preservation patient decision aids for cancer patients. <i>Psycho-Oncology</i>, 28(3), 459-467. o de Man, A. M., Rashedi, A., Nelen, W., Anazodo, A., Rademaker, A., de Roo, S., ... & Woodruff, T. (2018). Female fertility in the cancer setting: availability and quality of online health information. <i>Human Fertility</i>, 1-9. • Why did the authors decide to use the paper based (online PDF) Australian decision aid compared to a web-based resource? Is there a reason why a paper based tool would be more beneficial for young women with breast cancer in Portugal? • Page 13, line 8 – what are the age ranges for the different focus groups? • Will the team continue to conduct focus groups if they do not reach saturation between the groups planned? Is the team aiming for saturation between the population specific groups or between all the focus groups together? • In the contributors section, it is all written in past tense which makes it seem as though work has already been completed. E.g., “LT participated in the decision aid development and in decision aid revision.” Has the decision aid already been created using the steps outlined in the proposal? <p>Minor Comments</p> <ul style="list-style-type: none"> • Study dates are not provided in the paper as required by the journal • Authors switch back and forth between calling the DA a ‘reproductive health-related decision aid’ and a ‘fertility-related decision aid’ for consistency they could select one term and use throughout manuscript • Check grammar and ensure all acronyms are used throughout the paper once defined. <ul style="list-style-type: none"> o Page 4, line 55, Strengths and Limitations of the Study – last bullet point is unclear. Does ‘its’ refer to the DA the team is creating? o Page 6, line 31 – ‘cancer’s’ should be ‘cancer’ o Page 6, line 29-35 – the last sentence is unclear “likelihood the threat to future fertility” o Page 9, line 52 – last sentence is unclear “out study is pioneer in Portugal” and ‘DA’ should be ‘DAs’ o Page 10, line 38 – ‘illustrate’ should be ‘illustrates’ o Page 10, line 49 – ‘consists of’ should be ‘is’ o Page 12, lines 24 – delete ‘patients’ o Page 13, line 38 – ‘ago’ should be changed to ‘before the study’ or a similar term o Page 14, line 38 – quality of life was already defined and an acronym assignment so can change to ‘QoL’ o Page 14, line 43 – ‘USA’ should be ‘United States of America’ as this has acronym has not been defined previously o Page 15, line 52-57 – sentence is unclear, ‘contributing’ and ‘contribute’ do not seem to be the appropriate words for this sentence o Page 16, line 8 – ‘Oncofertility’ does not need to be capitalized
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REVIEWER	Shanna Logan UNSW, Australia
REVIEW RETURNED	17-Apr-2019

GENERAL COMMENTS	<p>This is overall a succinct protocol for an important study tool that will likely have local benefit to Portuguese patients. The authors desire to adapt an existing evidence based protocol should be commended. This protocol is also important to allow other researchers, both in Portugal and internationally to be aware of the current adaptation. I have outlined a few minor revision suggestions below to improve grammar, overall readability, and to add depth to your literature review.</p> <ol style="list-style-type: none"> 1. Provide reference for page 6 line 13. 2. Alter grammar on page 6 line 31 to read: on a cancer treatments likely threat to future fertility and to... 3. Page 6 line 33 please define term fertility preservation. 4. Page 6 line 41 remove "in fact" and clarify patient group, e.g. women of reproductive age. 5. Page 6 line 50 define what was novel about the Portuguese sample compared to other regions? Your statement afterwards demonstrates no difference which is not a novelty. 6. Page 7 line 8 start new paragraph at "Currently" 7. Page 7 line 13 start new sentence at "Mostly". Please also define common methods of evidence based fertility preservation, including the recently non experimental ovarian tissue cryopreservation. Please also define that while it is recognised as preferential that preservation occurs prior to oncological treatment, that guidelines also recommend offering preservation at later stages of treatment if not earlier available (due to time pressure); however, that this may result in less optimal outcomes. 8. It is important to acknowledge briefly in your introduction the complex decision making processes that women must undertake are influenced by time pressure to undertake fertility preservation prior to oncological treatment, while simultaneously managing news of a new cancer diagnosis. Please also reference the statement on page 7 line 34. 9. Please acknowledge and include recent systematic review on fertility preservation decision aids in introduction to page 8 paragraph 2: Wang, Y., Anazodo, A. & Logan, S. (2018) Systematic review of fertility preservation patient decision aids for cancer patients. <i>Psycho-Oncology</i>, 28(3). 10. Page 9 line 52 alter grammar to read: study is a pioneer 11. Page 10 line 51 please specify age range for initial Australia DA 12. Page 12 line 24 sentence reads confusingly please restructure into separate sentences. E.g "...diagnosed with breast cancer, including patients, survivors and partners of breast cancer patients. The components of LV include..." All examples given are for survivors, is the content the same for other patient groups? In which case state "survivors/patients/partners" or similar. 13. Avoid repetition of inclusion criteria that is mirrored across groups and simply state that all participants across groups were required to be able to e.g. read and write in Portuguese language, page 13.
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REVIEWER	Verena Ehrbar University Hospital Basel, Switzerland
REVIEW RETURNED	18-Apr-2019

GENERAL COMMENTS	<p>Dear Author</p> <p>I was given the opportunity to review your manuscript on the study protocol about your planned study regarding the development of a Portuguese decision aid for breast cancer patients. the study is very interesting and very needed, however i have some comments on the manuscript. I hope that with these suggestions of revision, the editor will give you the opportunity to publish the study protocol. And I hope your study will be a success and a good addition to patient care in your country.</p> <p>Introduction:</p> <p>general: it is a pretty long introduction with a lot of repetitions. i would suggest to shorten it.</p> <p>page 6, line 55-60: you compare Portuguese women to US women with the point that no cultural difference exist. i'd suggest to add also other studies from other cultures to foster this part, that women regardless of their culture, state that fertility is important. cite i.eg. this study: https://www.ncbi.nlm.nih.gov/pubmed/28934899 or https://www.ncbi.nlm.nih.gov/pubmed/26802020</p> <p>page 7, line 34 pp: you mention some factors / barriers, however i'd suggest to add financial issues as well, as this has been shown in various paper to be a significant argument in decision-making.</p> <p>p 7, line 58: i'd move this part (it is pivotal that women are often unmet) up to page 7, line 29, at the end of this paragraph.</p> <p>p8, line 38: '...reduce the amount of time the provided needs to spend explaining...' --> DA should not replace the discussion with a specialist, so the aim should not be to reduce the time they need for discussion but to help patients in order that they can re-read the information again or prepare themselves for this discussion with reading the information on the DA. please change this sentence.</p> <p>p 8, line 40: please delete the sentence 'the development... is clinically valuable', in order to shorten the introduction.</p> <p>p8, line 59: you say that DA are still scarce and mention only the australian one. this is correct, however there have been a few more that have been developped over the last few years. please mention also the german DA (https://www.ncbi.nlm.nih.gov/pubmed/28759303) as well as the Dutch one (https://www.ncbi.nlm.nih.gov/pubmed/27848252). those have been evaluated, then there are other under development (Jones et al, from the UK / Woodard et al from the US). please add this information in the introduction.</p> <p>methods and analysis:</p> <p>p10, line 33: the first paragraph is a repetition of what was just written above, please delete or rewrite.</p> <p>p10, line 50-56: also here there is a repetition in these sentences</p> <p>p11, line 15: '...the DA produces a personalized summary...' <-- how can the DA produce a summary itself when it is a booklet? i understood that patients need to make this summary themselves with the ratings they inserted!?</p> <p>p12, line 48: please mention how big the sample should be. i see you stated this later on with the saturation principle, i'd like to see this earlier in this paragraph.</p> <p>general: i have not fully understood how you assess the LV within the focus group. please specify in the specific paragraph.</p>
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	<p>page 13, line 45: is the status of treatment for the patients of the 'partner focus group' important or not? please clarify.</p> <p>discussion:</p> <p>p15, line 3-5: please add the current review about DA: https://www.tandfonline.com/doi/abs/10.1080/23809000.2018.1503539</p> <p>p15, line 6-8: please cite examples for the paragraph from 'written materials ... DA for young breast cancer patients worldwide' - such as the two just mentioned DA from the netherlands / switzerland. or the ones from the US (Woodard et al / Bardford et al)</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer #1

We are very pleased that this reviewer considered our manuscript generally clear and provided a good overview of the proposed plan for the development and evaluation of the decision aid.

Reviewer's comments are addressed below:

MAJOR COMMENTS

1- The authors do not provide any information on the literature review process or how expert group consensus during the multidisciplinary panel will occur. This information should be added to Figure 1 to be consistent with the process planned for the focus group analysis (content analysis).

- o Will the authors adhere to the PRISMA checklist for the literature review? Authors should report on what databases they are searching for the review, year restrictions, inclusion/exclusion details, risk of study bias, data abstraction and synthesis plan.

- o What consensus strategy will the authors use with the multidisciplinary panel to determine what scientific and cultural aspects of the decision aid should be modified (e.g., Delphi)?

Our current work is the result of our previous research, which include a study about fertility attitudes of young Portuguese survivors of breast cancer (Gonçalves V et al. Childbearing across borders: Fertility and parenthood attitudes and decisions among breast cancer survivors in USA and Portugal. Breast. 2018; 40:16-22), in addition to two reviews: one systematic review about fertility attitudes in young breast cancer survivors (Gonçalves, V., Sehovic, I., Quinn, G. Childbearing attitudes and decisions of young breast cancer survivors: a systematic review. Human Reproduction Update 2014; 20: 279-292 PubMed) and a narrative review about fertility preservation issues for young breast cancer patients (Gonçalves, Quinn, G. Review of fertility preservation issues for young women with breast cancer. Human Fertility 2016; 19: 152-165 PubMed). For the current project, we have expanded and updated our knowledge gained from the above mentioned reviews and will conduct a narrative review of relevant guidelines for Fertility Preservation and DAs. This information will be used to inform the transcreation process of the DA. We anticipate when this review is complete that we will follow PRISMA guidelines, even though it is not a systematic review, and at that time we will report on the details (databases, inclusion, etc) in the data results in a publication. The multidisciplinary panel of experts in the field will then review the translated version of the DA for scientific and cultural adequacy and provide comments which will be used to edit the DA. Experts' reviews will be analyzed by the research team and any incongruences will be clarified with the experts, if needed, which makes it an iterative process. For clarity purposes, we have revised the manuscript with more details about the transcreation process and also made amendments to Figure 1.

2- The authors should include a reference for content analysis.

Following reviewer's suggestion, we have included the reference in the manuscript.

3- The authors can cite recent works on oncofertility resources identified in organizations and other decision aids available (examples below)

- o Wang, Y., Anazodo, A., & Logan, S. (2019). Systematic review of fertility preservation patient decision aids for cancer patients. *Psycho-Oncology*, 28(3), 459-467.

- o de Man, A. M., Rashedi, A., Nelen, W., Anazodo, A., Rademaker, A., de Roo, S., ... & Woodruff, T. (2018). Female fertility in the cancer setting: availability and quality of online health information. *Human Fertility*, 1-9.

Following reviewer's suggestions, we now include results of other evaluated decision aids and tools.

4- Why did the authors decide to use the paper based (online PDF) Australian decision aid compared to a web-based resource? Is there a reason why a paper based tool would be more beneficial for young women with breast cancer in Portugal?

We decided to use a developed and validated fertility related DA specifically designed for young breast cancer patients, given its efficacy has previously been documented in this population. Furthermore, one of the advantages of this tool is that its' original language is English, a language in which the majority of the research team is fluent. In addition, a paper based tool would be more easily and rapidly implemented in our clinical settings, since does not require access to the Internet by the clinician or the patient or a need for any specific device.

5- Page 13, line 8 – what are the age ranges for the different focus groups?

Eligible participants for all of the focus groups include women 18-45 years of age. Eligible partner participants can be any age. This information has been clarified in the text and the sentence "Patients will be grouped by age in the focus groups", has been deleted, for clarity purposes.

6- Will the team continue to conduct focus groups if they do not reach saturation between the groups planned? Is the team aiming for saturation between the population specific groups or between all the focus groups together?

Yes, the goal of the focus groups is to achieve saturation. To this end, we will aim for thematic saturation (where data collection does not generate substantially new information and the range of perspectives appear to be completely covered) between the population specific focus groups. For clarity purposes, we have amended the sentence in the analysis section of the manuscript.

7- In the contributors section, it is all written in past tense which makes it seem as though work has already been completed. E.g., "LT participated in the decision aid development and in decision aid revision." Has the decision aid already been created using the steps outlined in the proposal?

Following reviewer's suggestion, we have altered the text in the contributors section.

MINOR COMMENTS

1- Study dates are not provided in the paper as required by the journal.

This information was moved to the methods section of the manuscript.

2- Authors switch back and forth between calling the DA a 'reproductive health-related decision aid' and a 'fertility-related decision aid' for consistency they could select one term and use throughout manuscript

In order to comply with reviewers' recommendation, we adopted the term "fertility-related decision aid" and used throughout the manuscript.

3- Check grammar and ensure all acronyms are used throughout the paper once defined.
Following reviewer's suggestion, we have checked the grammar and all acronyms used throughout the paper.

- o Page 4, line 55, Strengths and Limitations of the Study – last bullet point is unclear. Does 'its' refer to the DA the team is creating?

The word "its" refers to fertility discussions. For clarity purposes, this sentence was re-written .

- o Page 6, line 31 – 'cancer's' should be 'cancer'

This was amended in the text.

- o Page 6, line 29-35 – the last sentence is unclear "likelihood the threat to future fertility"

This was amended according to reviewer's suggestion.

- o Page 9, line 52 – last sentence is unclear "out study is pioneer in Portugal" and 'DA' should be 'DAs'

This was amended according to reviewer's suggestion. "DA" was substituted by "DAs".

- o Page 10, line 38 – 'illustrate' should be 'illustrates'

This was amended in the text.

- o Page 10, line 49 – 'consists of' should be 'is'

This was amended in the text.

- o Page 12, lines 24 – delete 'patients'

This was amended in the text.

- o Page 13, line 38 – 'ago' should be changed to 'before the study' or a similar term

This was amended in the text.

- o Page 14, line 38 – quality of life was already defined and an acronym assignment so can change to 'QoL'

This was amended in the text.

- o Page 14, line 43 – 'USA' should be 'United States of America' as this has acronym has not been defined previously

We defined the acronym for United States of America in the Introduction section; therefore, we kept USA in the Discussion section.

- o Page 15, line 52-57 – sentence is unclear, 'contributing' and 'contribute' do not seem to be the appropriate words for this sentence

This sentence was re-written in the text for clarity purposes.

- o Page 16, line 8 – 'Oncofertility' does not need to be capitalized

This was amended in the text.

Reviewer #2

We are very pleased that the reviewer recognizes that this protocol is for an important study tool that will likely have local benefit to Portuguese patients.

Reviewers' comments are addressed below:

1. Provide reference for page 6 line 13.

This reference has been added to the manuscript.

2. Alter grammar on page 6 line 31 to read: on a cancer treatments likely threat to future fertility and to...

We have corrected this and other grammar issues throughout the manuscript.

3. Page 6 line 33 please define term fertility preservation.

We apologize this was not clear. This information is now expanded in the text.

4. Page 6 line 41 remove "in fact" and clarify patient group, e.g. women of reproductive age.

According to reviewer's suggestion, these was amended in the text.

5. Page 6 line 50 define what was novel about the Portuguese sample compared to other regions? Your statement afterwards demonstrates no differenced which is not a novelty.

Our intention was not to state that the sample of Portuguese women was different from other regions, but to highlight that our previous study provided new data and knowledge about Portuguese women, which previously had not been documented. Further, it was refreshing to note Portuguese women feel no differently than women in the USA and other countries. Prior to this study, there had been no data on young Portuguese women's attitudes towards fertility after a breast cancer diagnosis. The results corroborated the premise that, as in other countries, fertility issues are important and must be acknowledged in Portuguese clinical settings.

6. Page 7 line 8 start new paragraph at "Currently"

This has been amended in the manuscript

7. Page 7 line 13 start new sentence at "Mostly". Please also define common methods of evidence based fertility preservation, including the recently non experimental ovarian tissue cryopreservation. Please also define that while it is recognized as preferential that preservation occurs prior to oncological treatment, that guidelines also recommend offering preservation at later stages of treatment if not earlier available (due to time pressure); however, that this may result in less optimal outcomes.

We have edited the manuscript to clearly state the difference between experimental and standards of care. We are unaware of any guidelines that suggest Fertility Preservation can be conducted for women, during active treatment.

8. It is important to acknowledge briefly in your introduction the complex decision making processes that women must undertake are influenced by time pressure to undertake fertility preservation prior to oncological treatment, while simultaneously managing news of a new cancer diagnosis. Please also reference the statement on page 7 line 34.

The complex decision making involving fertility that young breast cancer patients face at the time of diagnosis was briefly highlighted and added to the introduction section. The statement on page 7, line 34 was referenced.

9. Please acknowledge and include recent systematic review on fertility preservation decision aids in introduction to page 8 paragraph 2:

Wang, Y., Anazodo, A. & Logan, S. (2018) Systematic review of fertility preservation patient decision aids for cancer patients. *Psycho-Oncology*, 28(3).

This recent systematic review was acknowledged and included in the introduction. We retained the acknowledgment of the above mentioned review in the conclusion section of our manuscript.

10. Page 9 line 52 alter grammar to read: study is a pioneer
This was amended in the text.

11. Page 10 line 51 please specify age range for initial Australia DA
This information was added in the text.

12. Page 12 line 24 sentence reads confusingly please restructure into separate sentences. E.g "...diagnosed with breast cancer, including patients, survivors and partners of breast cancer patients. The components of LV include..." All examples given are for survivors, is the content the same for other patient groups? In which case state "survivors/patients/partners" or similar. In order to comply with reviewers' recommendation, this information was clarified in the text.

13. Avoid repetition of inclusion criteria that is mirrored across groups and simply state that all participants across groups were required to be able to e.g. read and write in Portuguese language, page 13.
This was amended in the text as suggested.

Reviewer #3

We are very pleased that the reviewer finds our study interesting and very needed.

Reviewers' comments are addressed below:

Introduction:

general: it is a pretty long introduction with a lot of repetitions. i would suggest to shorten it.
Following reviewer' suggestion, we have revised the introduction, deleted repeated information, in order to shorten the introduction.

page 6, line 55-60: you compare Portuguese women to US women with the point that no cultural difference exist. i'd suggest to add also other studies from other cultures to foster this part, that women regardless of their culture, state that fertility is important. cite i.e.g. this study: <https://www.ncbi.nlm.nih.gov/pubmed/28934899> or <https://www.ncbi.nlm.nih.gov/pubmed/26802020>

As suggested by the reviewer, we have added these studies to the introduction.

page 7, line 34 pp: you mention some factors / barriers, however i'd suggest to add financial issues as well, as this has been shown in various paper to be a significant argument in decision-making. We have added financial issues to the factors that play a role at the decision-making process, however, as our targeted population with this study is young Portuguese breast cancer patients, we have added as well some information regarding costs of fertility preservation techniques for cancer patients in Portugal, which are covered by the National Health System, unless the patient opts for a private health institution.

p 7, line 58: i'd move this part (it is pivotal that women are often unmet) up to page 7, line 29, at the end of this paragraph.

The sentence outlined by the reviewer was moved as suggested.

p8, line 38: '...reduce the amount of time the provided needs to spend explaining...' --> DA should not replace the discussion with a specialist, so the aim should not be to reduce the time they need for discussion but to help patients in order that they can re-read the information again or prepare themselves for this discussion with reading the information on the DA. please change this sentence. We have acknowledged reviewer's comment and deleted this part of the sentence in the introduction.

p 8, line 40: please delete the sentence 'the development... is clinically valuable', in order to shorten the introduction.

We have acknowledged reviewer's comment and deleted this part of the sentence in the introduction.

p8, line 59: you say that DA are still scarce and mention only the australian one. this is correct, however there have been a few more that have been developped over the last few years. please mention also the german DA (<https://www.ncbi.nlm.nih.gov/pubmed/28759303>) as well as the Dutch one (<https://www.ncbi.nlm.nih.gov/pubmed/27848252>). those have been evaluated, then there are other under development (Jones et al, from the UK / Woodard et al from the US). please add this information in the introduction.

Following reviewer suggestion, we have included this information in the introduction.

methods and analysis:

p10, line 33: the first paragraph is a repetition of what was just written above, please delete or rewrite. This sentence has been deleted from the manuscript.

p10, line 50-56: also here there is a repetition in these sentences

We have revised this sentence and repeated information was deleted.

p11, line 15: '...the DA produces a personalized summary...' <-- how can the DA produce a summary itself when it is a booklet? i understood that patients need to make this summary themselves with the ratings they inserted!?

For clarity purposes, this sentence was amended in the manuscript.

p12, line 48: please mention how big the sample should be. i see you stated this later on with the saturation principle, i'd like to see this earlier in this paragraph.

Following reviewer recommendation, this information was added earlier. In qualitative research the focus is on achieving saturation. We anticipate and cite the number of participants likely needed to achieve saturation.

general: i have not fully understood how you assess the LV within the focus group. please specify in the specific paragraph.

We have clarified the information regarding Learner Verification in text.

page 13, line 45: is the status of treatment for the patients of the 'partner focus group' important or not? please clarify.

As suggested by the reviewer, we have clarified this information in the manuscript.

discussion:

p15, line 3-5: please add the current review about

DA: <https://www.tandfonline.com/doi/abs/10.1080/23809000.2018.1503539>

We have added the review to the manuscript.

p15, line 6-8: please cite examples for the paragraph from 'written materials ... DA for young breast cancer patients worldwide' - such as the two just mentioned DA from the netherlands / switzerland. or the ones from the US (Woodard et al / Bardford et al)

Following reviewer suggestions, we have added these citations to the sentence.

VERSION 2 – REVIEW

REVIEWER	Nancy Baxter St. Michael's Hospital, Unity Health Toronto Canada
REVIEW RETURNED	09-Jun-2019

GENERAL COMMENTS	<p>Goncalves et al., made substantial revisions and overall the revisions improved the clarity and quality of the protocol. The proposed work will create a decision aid that will greatly benefit young women diagnosed with breast cancer and their health care providers in Portugal.</p> <p>The authors have addressed most of our comments in the responses but we there could be a few minor changes to the actual protocol prior to publication. The authors provided a detailed rationale for the decision to use the Australian decision aid to help create their aid in the response but did not include this in the protocol. Including the rationale in the protocol (potentially at the end of the first paragraph on pg. 10 or introduction), especially as they now outlined the other fertility decision tools that are currently available for young breast cancer patients, would strengthen this work. While the authors clarified the plan to complete a narrative review of the fertility guidelines/DAs for young women with cancer to inform the first round of revisions to the DA, they did not include the steps for the narrative review in the protocol (e.g., databases to search, grey literature, etc.). If these details are known, describing them would be important to include in the protocol in addition to the detailed methods for the DA acceptability assessment planned. Additionally, the revised Figure 1 noted in the responses was not included in the revised manuscript.</p>
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REVIEWER	Shanna Logan University of New South Wales, Australia
REVIEW RETURNED	28-May-2019

GENERAL COMMENTS	<p>The authors have addressed all queries brought forth by the reviewers. As such the manuscript reads more comprehensively and gives a clearer definition for both its justification and methodology utilized. The manuscript will make a useful addition to the literature in both informing other clinicians of important work being done or guiding researchers in similar translation processes.</p>
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REVIEWER	Verena Ehrbar University Hospital Basel, Switzerland
REVIEW RETURNED	28-May-2019
GENERAL COMMENTS	the authors have mainly taken into account the comments from the reviewers and the manuscript seems now more complete and understandable. from my point of view, i have no concerns anymore for publishing it. it is a study protocol, so there are no results yet and i look very forward to see the upcoming process of this planned study. i encourage publishing also study protocols and preliminary data of research fields that are not yet well known.

VERSION 2 – AUTHOR RESPONSE

Reviewer #1

Reviewers' comments are addressed below:

1-The authors provided a detailed rationale for the decision to use the Australian decision aid to help create their aid in the response but did not include this in the protocol. Including the rationale in the protocol (potentially at the end of the first paragraph on pg. 10 or introduction), especially as they now outlined the other fertility decision tools that are currently available for young breast cancer patients, would strengthen this work.

Following reviewers suggestion, we now include this information in the introduction.

2- While the authors clarified the plan to complete a narrative review of the fertility guidelines/DAs for young women with cancer to inform the first round of revisions to the DA, they did not include the steps for the narrative review in the protocol (e.g., databases to search, grey literature, etc.). If these details are known, describing them would be important to include in the protocol in addition to the detailed methods for the DA acceptability assessment planned.

We have added the following information to page 11 "The narrative review will follow standard PRISMA methods using Boolean search operators and will include quantitative, qualitative and mixed methods peer-reviewed publications by searching the databases: Medline, EMBASE, ISI Web of Knowledge, PubMed and PsychLit."

3- The revised Figure 1 noted in the responses was not included in the revised manuscript.

The revised figure was uploaded in this revision round.